

August 18, 2015



# **Tonix Pharmaceuticals Presents on the Development of TNX-102 SL for Post-Traumatic Stress Disorder (PTSD) at the 2015 Military Health System Research Symposium**

## **TNX-102 SL is Currently Being Evaluated in Patients With Military-Related PTSD**

NEW YORK, Aug. 18, 2015 (GLOBE NEWSWIRE) --[Tonix Pharmaceuticals Holding Corp.](#) (NASDAQ:TNXP) ("Tonix") today presented an overview of its development of TNX-102 SL (cyclobenzaprine HCl sublingual tablets) for PTSD, including a review of the design of the AtEase Clinical Study, at the [2015 Military Health System Research Symposium](#) held in Fort Lauderdale, Florida.

Gregory M. Sullivan, M.D., Tonix's Chief Medical Officer, presented a poster entitled, *"The AtEase Study: An Evaluation of the Efficacy of a Low Dose, Bedtime, Sublingual Formulation of Cyclobenzaprine (TNX-102 SL tablet) for the Treatment of Military-Related PTSD"* (Abstract ID: MHSRS-15-0900; Poster ID: 1220).

"PTSD is a serious chronic illness, and many of those with military-related PTSD do not respond to existing treatments. There is an urgent unmet medical need for this patient population," said Seth Lederman, M.D., chairman and CEO of Tonix. "Recruitment into AtEase recently reached 50% of its target enrollment goal of 220 patients, and we expect to report top line data in the first half of 2016."

### **About the AtEase Clinical Study**

The [AtEase Clinical Study](#) is a randomized, double-blind, placebo-controlled clinical trial to evaluate the efficacy and safety of TNX-102 SL for the treatment of patients with military-related PTSD. The trial is expected to enroll approximately 220 participants who will receive study medication daily at bedtime for twelve weeks. The primary efficacy endpoint will evaluate the performance of TNX-102 SL 2.8 mg on the total Clinician-Administered PTSD Scale for DSM-5 (CAPS-5) score. Tonix expects to report top-line results in the first half of 2016. To learn more, please visit [www.ateasestudy.com](http://www.ateasestudy.com).

### **About TNX-102 SL**

[TNX-102 SL](#) efficiently delivers a low dose of cyclobenzaprine to the bloodstream via

sublingual (under the tongue) absorption, and is designed for chronic use at bedtime to improve sleep quality. As a multifunctional agent with antagonist activities at the serotonin-2A, alpha-1 adrenergic, and histamine H1 receptors, TNX-102 SL is intended to provide broad-spectrum symptom improvement in PTSD by targeting sleep and the stress response.

### **About Post-Traumatic Stress Disorder**

PTSD afflicts approximately 8.5 million Americans each year, and its prevalence rate in the military population is higher than that among civilians. Both of the drugs approved by the U.S. Food and Drug Administration (FDA) for PTSD lack reliable evidence of efficacy in combat-related trauma and carry suicidality warnings.

### **About Tonix Pharmaceuticals Holding Corp.**

Tonix is dedicated to the invention and development of novel pharmaceutical products for medical conditions that it believes have broad societal impact, that are not well served by currently available therapies and that represent large potential commercial opportunities. Tonix's Tonmya™ is currently being evaluated in the Phase 3 AFFIRM study in fibromyalgia. TNX-102 SL, the same proprietary product candidate as Tonmya, is currently being evaluated in the Phase 2 AtEase study in post-traumatic stress disorder. A Phase 2 proof-of-concept study of TNX-201 in episodic tension-type headache is ongoing. This press release and further information about Tonix can be found at [www.tonixpharma.com](http://www.tonixpharma.com).

*TNX-102 SL and TNX-201 are Investigational New Drugs and have not been approved for any indications.*

### **Safe Harbor / Forward-Looking Statements**

*Certain statements in this press release are forward-looking within the meaning of the Private Securities Litigation Reform Act of 1995. These statements may be identified by the use of forward-looking words such as "anticipate," "believe," "forecast," "estimate" and "intend," among others. These forward-looking statements are based on Tonix's current expectations and actual results could differ materially. There are a number of factors that could cause actual events to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, substantial competition; our possible need for additional financing; uncertainties of patent protection and litigation; uncertainties of government or third party payor reimbursement; limited research and development efforts and dependence upon third parties; and risks related to failure to obtain FDA clearances or approvals and noncompliance with FDA regulations. As with any pharmaceutical under development, there are significant risks in the development, regulatory approval and commercialization of new products. Tonix does not undertake an obligation to update or revise any forward-looking statement. Investors should read the risk factors set forth in the Annual Report on Form 10-K for the year ended December 31, 2014 and Quarterly Report on Form 10-Q for the period ended June 30, 2015, as filed with the Securities and Exchange Commission (the "SEC") on February 27, 2015 and August 7, 2015, respectively, and future periodic reports filed with the SEC on or after the date hereof. All of Tonix's forward-looking statements are expressly qualified by all such risk factors and other cautionary statements. The information set forth herein speaks only as of the date hereof.*

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